UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

SEALED, Plaintiffs,	§	Civil Action No. 13-1081
	§	FILED *IN CAMERA* AND UNDER SEAL Pursuant to 31 U.S.C. §3730(b)(2)
v.	§	
SEALED, Defendants.	§	

FILED UNDER SEAL

(ATTENTION SEAL CLERK)

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

UNITED STATES OF AMERICA and STATES OF TEXAS, COLORADO, FLORIDA, GEORGIA, ILLINOIS, LOUISIANA, MARYLAND, NEW JERSEY, NORTH CAROLINA, and OKLAHOMA; COMMONWEALTH OF VIRGINIA; STATE OF WASHINGTON; and THE DISTRICT OF COLUMBIA, *ex rel.*	§	**Civil Action No.** _____
MICHAEL VAUGHN, THEODORE FREEMAN, WILLIAM MCKENNA, and WESLEY STAFFORD, Relators, **Plaintiffs,**	§	**FILED *IN CAMERA* AND UNDER SEAL** **Pursuant to 31 U.S.C. §3730(b)(2)**
v.	§	
UNITED BIOLOGICS, LLC, d/b/a UNITED ALLERGY SERVICES f/k/a UNITED ALLERGY LABS; SMART ALLERGY LABS; and ALLERGY PRACTICE CONSULTING GROUP d/b/a ALLERTA CORP., **Defendants.**	§	**Demand for a Jury Trial**

FALSE CLAIMS ACT COMPLAINT

I.
INTRODUCTION

1. Relators Michael Vaughn ("Dr. Vaughn"), Theodore Freeman ("Dr. Freeman"), William McKenna ("Dr. McKenna"), and Wesley Stafford ("Dr. Stafford") (collectively "Relators") bring this action on behalf of the United States of America ("U.S." or "federal government") and the States of Texas, Colorado, Florida, Georgia, Illinois, Louisiana, Maryland, New Jersey, North Carolina, and Oklahoma; the Commonwealth of Virginia, the State of Washington; and the District of Columbia, (collectively "the States,") and on their own behalf

(the U.S. and the States may be referred to jointly as the "government" and the U.S., the States, and Relators may be referred to collectively as "Plaintiffs"), against Defendants, United Biologics, LLC d/b/a United Allergy Services and f/k/a/ United Allergy Labs, Smart Allergy Labs, and Allergy Practice Consulting Group d/b/a Allerta Corp. (collectively, "Defendants.")

2. Each Relator is a board certified allergist licensed to practice medicine in Texas, and actively engaged in the practice of diagnosing, testing and treating individuals for allergies within the state of Texas. Through their medical practices and their involvement in various medical societies, the Relators learned of Defendants' illegal schemes.

3. The Defendants market, own and/or operate allergy centers ("Remote Allergy Centers") placed in numerous offices and clinics of primary care physicians and other physicians (collectively "PCPs") throughout the country. Defendants contract with PCPs to provide allergy testing and treatment services to the PCPs' patients. These services are provided by employees and agents of Defendants within a designated space at the PCPs' offices. Many of the PCPs' patients receive healthcare coverage through the States' Medicaid programs (paid with both state and federal funds), the federal Medicare and Tricare/Champus programs, and other federally-funded government healthcare programs (sometimes collectively referred to herein as "Government Healthcare Programs.")

4. Defendants are engaged in at least three illegal schemes. First, Defendants provide PCPs with illegal kickbacks in violation of the federal Anti-Kickback Statute, inducing PCPs to contract with the Defendants to set up Remote Allergy Centers in the PCPs' offices or clinics, and inducing the PCPs to refer patients to Defendants' Remote Allergy Centers. These kickbacks take the form of fee-splitting arrangements based on volume and other illegal inducements. Second, the Defendants provide or cause to be provided unnecessary medical

treatment through the provision of allergen immunotherapy and improperly bill Government Healthcare Providers or cause Government Healthcare Providers to be improperly billed for these treatments. Third, Defendants improperly bill Government Healthcare Providers or cause Government Healthcare Providers to be improperly billed for the "services" they provide; specifically Defendants improperly bill or induce the PCPs to improperly bill for the mixing and dilutions of allergens and for sublingual immunotherapy, an unapproved allergy treatment method which involves placing liquid drops of allergens underneath the patient's tongue. Each of these three schemes violates the federal False Claims Act and the States' False Claims Acts, by causing the submission of false claims to and other unlawful acts against Government Healthcare Programs through Defendants' false claims, false statements, false reports, false certifications, and other wrongful acts, as described in greater detail below.

5. Defendants' specific wrongful acts include, in addition to other acts described herein, billing or causing the billing to Government Healthcare Programs for: kickback-tainted healthcare resulting from illegally inducing PCPs to contract with them to provide unnecessary medical services, such as skin testing all patients with a large and invariant number of allergens, the selection of which is without regard to the patients' medical history; providing immunotherapy to patients without any determination of medical necessity; providing ineffective subcutaneous immunotherapy as a result of the immunotherapy serum containing allergen contents at levels below the "probable effective" recommended concentrations; using an excessive number of antigen dilutions and an unproven schedule of immunotherapy, requiring an unusually high number of injections, to allow for an unusually high number of doses to be billed for the extract; and providing unapproved sublingual immunotherapy which is billed as if approved subcutaneous immunotherapy injections had been provided.

6. This action is filed as a result of the Defendants' violations of 31 U.S.C. §§3729 *et seq.* (the "federal False Claims Act" or the "FCA"), 42 U.S.C. §1320a-7b (the "federal Anti-Kickback Statute" or "AKS") and the Texas Medicaid Fraud Prevention Act, Texas Human Resource Code §§36.001 *et seq.* [the "Texas Medicaid Fraud Prevention Act" or "TMFPA"]; the Colorado Medicaid False Claims Act, C.R.S. 25.5-4-305 *et seq.* ["Colorado FCA"]; the Florida False Claims Act, FLA. STAT. Ch. 68.081 *et seq.* ["Florida FCA"]; the Georgia False Medicaid Claims Act, GA. CODE ANN. §§49-4-168.1 *et seq.* ["Georgia FCA"]; the Illinois Whistleblower Reward and Protection Act, 740 ILL. COMP. STAT. §175/1 *et seq.* ["Illinois FCA"]; the Louisiana Medical Assistance Programs Integrity Law, LA. REV. STAT. ANN. §§46:439.1 *et seq.* ["Louisiana FCA"]; the Maryland False Claims Act, MD. Health-General Code §2-601 – 2-611 *et seq.* ["Maryland FCA"]; the New Jersey State False Claims Act, N.J. STAT. §2A:32C-1 *et seq.* ["New Jersey FCA"]; the North Carolina False Claims Act, N.C. GEN. STAT. §§1-605 – 1-618 *et seq.* ["North Carolina FCA"]; the Oklahoma Medicaid False Claims Act, OKLA. STAT. tit. 63 §§5053.1 *et seq.* ["Oklahoma FCA"]; the Washington State, RCW 74.09.210 *et seq.* ["Washington FCA"]; the Virginia Fraud Against Taxpayers Act, Code of Virginia §8.01-216.1 *et seq.* ["Virginia FCA"]; and the District of Columbia False Claims Act, D.C. CODE ANN., 2-308.14 *et seq.* ["D.C. FCA"]; collectively, the "State FCAs").

7. As a direct result of Defendants' improper practices in violation of the FCA, AKS, and the State FCAs, the U.S. and States' treasuries have been damaged in a substantial amount yet to be determined.

8. Plaintiffs seek treble damages, civil penalties, and other relief arising from Defendants' false claims made in violation the federal FCA and Defendants' unlawful acts made in violation of the State FCAs.

9. Relators possess direct and independent knowledge about Defendants' wrongful acts against the federal and state governments by submitting false claims and committing other unlawful acts with respect to the Government Healthcare Programs. If a public disclosure of Relators' allegations was made prior to filing this suit, which Relators deny, Relators are nevertheless the original source of any such allegations or disclosures.

10. Prior to filing this lawsuit, on April 4, 2013, Relators voluntarily disclosed substantially all material evidence and information the Relators possess by serving a Disclosure Statement and exhibits on the Attorney General of the United States; the U.S. Attorney for the Southern District of Texas; Assistant U.S. Attorney Andrew Bobb; the Texas Attorney General; and Texas Assistant Attorney General Susan Miller; the Colorado Attorney General; the Florida Attorney General; the Florida CFO of the Department of Financial Services; the Georgia Attorney General; the Illinois Attorney General; the Louisiana Attorney General and the Louisiana Secretary, Dept of Health & Hospitals; the Maryland Attorney General; the New Jersey Attorney General; the North Carolina Attorney General; the Oklahoma Attorney General; the Attorney General for the Commonwealth of Virginia; the Washington Attorney General; and the District of Columbia Attorney General.

II.
PARTIES

A. Plaintiffs

11. Relators bring this action on behalf of the United States and the States of Texas, Colorado, Florida, Georgia, Illinois, Louisiana, Maryland, New Jersey, North Carolina, Oklahoma, the Commonwealth of Virginia, Washington, and the District of Columbia, and themselves pursuant to the FCA and the State FCAs.

12. **Relator Michael P. Vaughn** ("Dr. Vaughn") is a United States citizen residing in San Antonio, Texas. Since 2004, Dr. Vaughn has been practicing with Alamo Asthma & Allergy, and Alamo Asthma & Allergy Associates, P.A. Alamo Asthma & Allergy is Dr. Vaughn's sole proprietorship and Alamo Asthma & Allergy Associates, P.A. is a professional association in which Dr. Vaughn and his wife Dr. Adrianne Vaughn are co-owners. Dr. Vaughn received his Bachelor of Science in Microbiology from St. Bonaventure University in 1980. He then matriculated to the Medical College of Virginia where in 1983 he received a PH.D. in Microbiology & Immunology and in 1987 received his M.D. After completing his medical training, Dr. Vaughn served as the Chief of Medicine Services at the United States Air Force hospital at the Hill Air Force Base in Utah. From 1995 to 2004, Dr. Vaughn worked primarily as an emergency medical doctor for the Baptist Health System. In 1995, Dr. Vaughn became board certified in Allergy, Asthma and Immunology. Dr. Vaughn is also board certified in internal medicine. While working with the Baptist Health System, Dr. Vaughn also served as an associate professor at the University of Texas Health Science Center and practiced one day a week in their allergy clinic as a volunteer. Additionally, Dr. Vaughn practiced at the Audie Murphy Veterans Affairs Hospital until he began his own practice in 2004. Dr. Vaughn is a member of the Texas Allergy, Asthma, and Immunology Society ("TAAIS"), the American Academy of Allergy, Asthma, and Immunology ("AAAAI"), and the Joint Council of Allergy, Asthma, and Immunology ("JCAAI"). TAAIS currently represents more than 230 board-certified allergists and immunologists in Texas. TAAIS promotes the highest standards in allergy and immunology by (1) improving the care of patients suffering from allergic, asthmatic, and immunologic disorders, (2) promoting patient and physician education on allergic, asthmatic and immunologic disorders, and (3) increasing the awareness among physicians and the general

public alike about the subspecialty of allergy and immunology. Dr. Vaughn also served as the president of the San Antonio Allergy Society from 2002 to 2003. In the course of his work as a board-certified allergist, Dr. Vaughn has discovered evidence of the illegal schemes discussed herein, and particularly evidence of Defendants' behavior designed to provide unnecessary medical services to patients and to cause the filing of false claims to Government Healthcare Programs for these services.

13. **Relator Theodore Monroe Freeman** ("Dr. Freeman") is a United States citizen residing in San Antonio, Texas. A retired United States Air Force colonel, Dr. Freeman currently owns and practices with the San Antonio Asthma and Allergy Clinic. He received his Bachelor of Science from Duke University in 1977 and his M.D. from the University of South Florida College of Medicine in 1980. In 1983, Dr. Freeman became a board certified internal medicine practitioner and in 1987 received his allergy and immunology board certification from the American Board of Allergy & Immunology. He also received special certification in diagnostic laboratory immunology in 1988. Dr. Freeman has held various positions throughout his 33-year career and has served in numerous prestigious roles, including acting as a consultant to the United States Surgeon General in Allergy and Immunology from August 1997 to July 2001. He is also actively involved in numerous scientific societies and professional organizations. Since 1994, Dr. Freeman has been a member of the TAAIS. From 2003 – 2007, he was a member of the TAAIS Board of Governors and in 2010 and 2011 he served as the Secretary-Treasurer for TAAIS. Dr. Freeman is currently TAAIS's President-Elect and will become the President in 2014. Dr. Freeman also is a member of the Board of Governors for AAAAI, and has been a member of the Board of Governors for the Federation of Region, State and Local Allergy, Asthma, and Immunology Societies. Dr. Freeman is a case reviewer for the

Texas State Medical Board ("TMB"). In this capacity, he reviewed complaints received by the TMB about physicians practicing allergy and immunology in the State of Texas. In the course of his work as a board-certified allergist and a member of the TAAIS board, as well as his work as an expert witness on behalf of Jean-Denis Boucher, M.D. in a lawsuit filed against him by UAL, Dr. Freeman discovered the wrongful and illegal schemes discussed herein.

14. **Relator William R. McKenna** ("Dr. McKenna") is a United States citizen residing in Harlingen, Texas. He received his Bachelor of Science in Biology from Baylor University in 1974 and his M.D. from Texas Tech University School of Medicine in 1977. In 1980, Dr. McKenna became board certified in internal medicine. He did his fellowship training in Allergy and Immunology at the University of Tennessee Health Science Center from 1980-1982, and in 1983 he received his board certification in allergy and immunology. Since 1982, he has also been in private practice with the professional association William R. McKenna, M.D., P.A. Additionally, from 1992 to the present, Dr. McKenna has served as a clinical associate professor of internal medicine at the University of Texas Health Science Center at San Antonio. He has also acted as a liaison for Medicaid in Texas concerning the proper delivery of immunotherapy, including the method of treatment and dosing protocols which are medically reasonable and necessary. Dr. McKenna is a fellow of the AAAAI, and a member of JCAAI, TAAIS, Texas Medical Association ("TMA") and American Medical Association ("AMA"). Additionally, he has served on the Board of Directors and as the Secretary-Treasurer, (2004 and 2005), President-Elect (2006 and 2007), President (2008 and 2009) and Past President of TAAIS. Dr. McKenna also holds the position of Governor Region 5 for the Regional State Local Allergy, Asthma & Immunology Societies, another prestigious professional society. Dr. McKenna is a member of AAAAI's Continuing Medical Education/Practice Improvement (CME/PI)

Committee. Dr. McKenna is a case reviewer for the TMB about physicians practicing allergy and immunology in the State of Texas. In the course of his work as a board-certified allergist, involvement with the TAAIS, and work with TMB, Dr. McKenna discovered the wrongful and illegal schemes discussed herein.

15. **Relator Wesley Warren Stafford** ("Dr. Stafford") is a United States citizen residing in Corpus Christi, Texas. Dr. Stafford has been privately practicing allergy and clinical immunology since 1988 with the Allergy and Asthma Center of Corpus Christi. He received his Bachelor of Arts in Biology from the University of Texas at Austin in 1974 and his M.D. from the University of Texas Medical Branch, Galveston in 1978. After completing his medical degree, Dr. Stafford served in the United States Army as a staff pediatrician at the William Beaumont Army Medical Center, as the director of the Child Protective Management Team in Nord Deutschland, Bremerhaven, Germany. He underwent fellowship training in Allergy and Immunology at the Fitzsimmons Army Medical Center in Colorado, and at the National Jewish Hospital for Respiratory Disease in Denver, Colorado. He finished his military career as the chief of Allergy and Immunology Service at the Martin Army Community Hospital in Fort Benning, Georgia. Dr. Stafford is board certified in pediatrics and in allergy and clinical immunology, a certification that he continues to maintain. He is actively involved in numerous scientific societies. Since 1988, Dr. Stafford has been a member of the TAAIS. He has served on the Board of Directors, as Secretary-Treasurer, as President-Elect, and currently serves as the President of TAAIS. He is also a member of JCAAI, a fellow with the AAAAI, and member of AAAAI's committee on continuing medical education. He is also a Fellow of the American College of Allergy, Asthma and Immunology. He is an Assistant Professor of Pediatrics of the Texas A&M Health Science Center and supervises the Allergy and Asthma training of Pediatric

Residents at the Driscoll Foundation Children's Hospital in Corpus Christi, Texas. Dr. Stafford is a past president of the Nueces County Medical Society and a delegate from Nueces County to the Texas Medical Association. Dr. Stafford has chaired the Continuing Medical Education Committee of the Texas Medical Association and currently remains active as a site reviewer for the Subcommittee of CME accreditation for the Texas Medical Association. He is also on the Texas Medical Association Council of Science and Public Health. Dr. Stafford is a case reviewer for the TMB. In this capacity, he reviewed complaints received by the TMB about physicians practicing allergy and immunology in the State of Texas. In the course of his work as a board-certified allergist and his involvement with TAAIS and TMB, Dr. Stafford discovered the wrongful and illegal schemes discussed herein.

B. Defendants

16. **Defendant United Biologics, LLC f/k/a United Allergy Labs and d/b/a United Allergy Services** ("UAL") is a Delaware Limited Liability Corporation. UAL contracts with PCPs to provide allergy testing and treatment services to the PCPs' patients. These services are provided by UAL employees and agents within a designated space at the PCPs' offices. UAL is in business across the country, including the following states which have state false claims acts: Texas, Colorado, Florida, Georgia, Illinois, Louisiana, Maryland, New Jersey, North Carolina, Oklahoma, Virginia, Washington, and the District of Columbia. The principal office of UAL is located in Texas; UAL operates throughout Texas and this District.

17. UAL was founded in 2009 as the combination of three separate but similar pre-existing entities – United Allergy of Georgia, United Allergy of Oklahoma and United Allergy of Texas. Dr. John Berberian, a chiropractor based out of Atlanta, GA, was the principal in United Allergy of Georgia. Dr. James Strader, another chiropractor, was the principal in United Allergy

of Texas, and Mr. Larry Smith was the principal of United Allergy of Oklahoma. The three entities were combined under the direction and supervision of Nicolas Hollis, a former international banker who currently serves as UAL's chief executive officer and *de facto* chief operating officer.

18. As of May 2012, UAL was operating in 16 states and the District of Columbia. UAL has been growing rapidly. At the beginning of 2010, UAL had 45 contracts with physicians and physician groups across the country; by the beginning of 2011, that number grew to 60 contracts with physicians and physician groups across the country; at the beginning of 2012, the number of contracts skyrocketed to 200; and a mere 5 months later, UAL added 100 more contracts, bringing the number to 300 in May 2012. Of these 300 contracts, approximately 125 to 150 are with Texas physicians.

19. As the number of contracts has grown, so have UAL's gross revenues. In 2011, UAL's annual gross revenues were approximately $30 million, and as of May 2012, the expected annual gross revenues were approximately $60 million.

20. Approximately 60 to 70% of patients seen in UAL's Remote Allergy Centers are placed on immunotherapy; in contrast, approximately 17% of the patients of Board Certified Allergists who are tested for allergies are placed on immunotherapy.

21. **Defendant Smart Allergy Labs, LLC** ("Smart Allergy" or "SAL") is a Texas Limited Liability Corporation. Like UAL, Smart Allergy contracts with PCPs across Texas to provide allergy testing and treatment services to the PCPs' patients. These services are provided by Smart Allergy employees and agents within a designated space at the PCPs' offices. The principal office of Smart Allergy is located in Texas. Smart Allergy operates throughout Texas and this District.

22. **Defendant Allergy Practice Consulting Group, Inc. d/b/a Allerta Corp.** ("Allerta") is a Delaware for-profit corporation authorized to do business in the state of Texas. Allerta contracts with PCPs across Texas to provide allergy testing and treatment services to the PCPs' patients. These services are provided by Allerta employees and agents within a designated space at the PCPs' offices. The principal office of Allerta is located in Texas. Allerta operates throughout Texas and this District.

III.
JURISDICTION

23. This action arises under the FCA, 31 U.S.C. §§3729 *et seq.*, and the Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§1331 and 1345.

24. This Court also has supplemental jurisdiction over the claims brought by Relators on behalf of themselves and on behalf of the States under the State FCAs pursuant to 28 U.S.C. §1367(a) and 31 U.S.C. §3732(b).

IV.
VENUE

25. Venue in this district is proper pursuant to 31 U.S.C. §3732(a) and 28 U.S.C. §1391(b) and (c) since one or more of the Defendants transact business in this district and/or one or more of the acts at issue occurred in this district.

V.
OVERVIEW OF GOVERNMENT HEALTHCARE PROGRAMS

A. Medicare

26. In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Health Insurance for the Aged and Disabled Program or the Medicare Program ("Medicare"), to pay for the costs of certain healthcare services. Entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. See 42 U.S.C. §§426, 426A. The United

States Department of Health and Human Services ("HHS") is responsible for the administration and supervision of Medicare, which is funded with taxpayer revenue. The Centers for Medicare and Medicaid Services ("CMS") is an agency of HHS and is directly responsible for the administration of the Medicare Program.

27. Part A of the Medicare Program authorizes payment for institutional care, including hospital, skilled nursing facility and home healthcare. See 42 U.S.C. §§1395c-1395i-4. Part B of the Medicare Program covers payment for physician services and certain outpatient services that Part A does not cover. The services allegedly provided by the Defendants are covered by Part B.

28. For a medical service to be covered by Medicare, the service must be medically necessary and supported by documentation. [Title XVIII of the Social Security Act §1862(a)(1)(A) and §1833(e)]. Moreover, Title XI of the Social Security Act mandates that the services provided meet professionally recognized standards of health care. These standards, called national coverage determinations ("NCD"), are typically promulgated by the Centers of Medicare and Medicaid Services ("CMS").

29. In recognition of significant impact that a patient's geographic location has on allergen immunotherapy, for the most part, CMS has elected not to establish an NCD for most allergen immunotherapies, instead instructing local Medicare contractors to establish their own local coverage determinations ("LCD").

30. For example, Novitas Solutions, Inc. is the Medicare contractor for Jurisdiction H, comprised of following relevant states: Texas, Louisiana, Colorado, and Oklahoma.

31. Novitas's LCD for allergen immunotherapy provides that Medicare coverage is allowed only if the following conditions are satisfied:

a. Positive allergic response to specified treatment allergens has been demonstrated by appropriate skin or in vitro testing;

b. The patient's hypersensitivity cannot be satisfactorily managed by medication or avoidance;

c. Antigen(s) is prepared for the patient individually and the antigen(s) content is based on appropriate skin testing or appropriate in vitro testing. The physician who prepared the antigen(s) has examined the patient, taken a history, and has determined a plan of treatment and a dosage regimen; and

d. Treatment is for one or more of the following:

i. IgE-mediated allergic rhinoconjunctivitis to clinically relevant allergen(s) and the allergic symptoms warrant the time and risk of allergen therapy based on the opinion of the treating physician.

ii. IgE-mediated allergic asthma to clinically relevant allergen(s) and the allergic symptoms warrant the time and risk of allergen therapy based on the opinion of the treating physician.

iii. IgE-mediated stinging insect hypersensitivity to clinically relevant allergen(s) and the allergic symptoms warrant the time and risk of allergen therapy based on the opinion of the treating physician.

32. The Novitas LCD goes on to specify which ICD-9 codes support a determination that immunotherapy is a medical necessity. These codes include 372.05 (acute atopic conjunctivitis), 477.0 (allergic rhinitis due to pollen), 477.8 (allergic rhinitis due to non-pollens like molds and house dust mites), and 493.00 (extrinsic asthma unspecified). This LCD was effective as of August 13, 2012 in Louisiana and October 2012 in Texas, Oklahoma, and Colorado. The LCDs in effect in these states prior to this date were substantially the same. [additional state information to be added]

33. An NCD has been established for Sublingual Immunotherapy ("SLIT"), which involves the administration of immunotherapy serums in the form of "drops" delivered under the tongue. The Medicare National Coverage Determination Manual expressly states that "Medicare does not cover such antigens if they are to be administered sublingually, i.e., by placing drops

under the patient's tongue. This kind of allergy therapy has not been proven to be safe and effective. *Antigens are covered only if they are administered by injection.*" (emphasis added). Medicare National Coverage Determination Manual, Ch. 1, Part 2, 110.9 – Antigens Prepared for Sublingual Administration.

34. Medicare does not cover claims for physician services where there is an AKS violation involved in the underlying transaction. Claims submitted to federal healthcare programs where a kickback was offered, paid, solicited, or accepted are false under the FCA.

> Providers that seek to bill Medicare must sign a Provider Agreement that states: I agree to abide by the Medicare laws, regulations and program instructions that apply to [me] … I understand that payment of a claim by Medicare is conditioned upon the claims and the underlying transaction complying with such laws, regulations and program instructions including, but not limited to Federal anti-kickback statute … and on the provider's compliance with all applicable conditions of participation in Medicare.

35. Defendants have submitted or caused to be submitted false claims to Medicare in violation of the FCA through their illegal schemes: (1) the kickback scheme, (2) the provision of unnecessary medical services, and (3) the improper billing for the mixing and dilution of allergens and improper billing of sublingual immunotherapy.

B. Medicaid

36. The Medicaid program is a health insurance program for qualified beneficiaries funded by federal and state taxpayer revenues enacted pursuant to Title XIX of the Social Security Act. 42 U.S.C. §§1396-1396v. Each state is permitted to design its own medical assistance plan. 42 U.S.C. § 1396a.

37. For example, the Texas Health and Human Services Commission (HHSC) administers the Texas Medicaid program. Texas Medicaid & Health Partnership (TMHP) serves as the fiscal agent for the Texas Medicaid program. TMHP periodically issues a Texas Medicaid

Provider Application, which includes the HHSC Medicaid Provider Agreement ("Medicaid Provider Agreement").

38. The Medicaid Provider Agreement for Texas requires that, as a condition for participation in the Texas Medicaid program, a provider must agree to comply with all terms and conditions of the Provider Agreement, including but not limited to:

> 1.2.3 This Agreement is subject to all state and federal laws and regulations relating to fraud, abuse and waste in health care and the Medicaid program.
>
> 1.3.1 Provider agrees to submit claims for payment in accordance with billing guidelines and procedures promulgated by HHSC, or other appropriate payor, including electronic claims. Provider certifies that information submitted regarding claims or encounter data will be true, accurate, and complete, and that the Provider's records and documents are both accessible and validate the services and the need for services billed and represented as provided. Further, ***Provider understands that any falsification or concealment of a material fact may be prosecuted under state and federal laws. . . .***

(Texas Medicaid Provider Enrollment Application, p. 6.2; emphasis added.).

39. Texas Medicaid defines allergen immunotherapy as "the parenteral[1] administration of allergenic extracts as antigens at periodic intervals, usually on an increasing dosage to a dosage that is maintained as maintenance therapy."

40. While allergen immunotherapy is generally covered by Texas Medicaid, it is subjected to several restrictions, including a limit of a total of 160 doses in a one-year period, unless the physician receives prior authorization by establishing medical necessity for the increased number of injections.

41. Other States' Medicaid programs also address the provision of allergen immunotherapy. For example, North Carolina Medicaid covers allergy immunotherapy by subcutaneous injection "for recipients with demonstrated hypersensitivity and/or severe and

[1] Parenteral refers to the introduction of a substance through a method other than orally, i.e., through subcutaneous or intramuscular injection.

debilitating symptoms that cannot be adequately managed by medications or avoidance of the allergen." Louisiana Medicaid program notes that allergen immunotherapy is "only recommended for allergic asthma, allergic rhinitis and conjunctivitis, and stinging insect allergy."

42. Through their kickback scheme, provision of unnecessary medical services, and the improper billing for the mixing and dilution of allergens and for sublingual immunotherapy, Defendants have submitted or caused to be submitted false claims to the States' Medicaid programs in violation of the FCA and the State FCAs.

C. Tricare/Champus

43. At all times relevant to this Complaint, Defendants, Defendants' physician partners, and many of Defendants' patients were enrolled in, and sought reimbursement from Tricare/Champus.

44. Tricare, previously known as the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), is a federal taxpayer-funded program that provides medical benefits to (a) the spouses and unmarried children of (1) active duty and retired service members, and (2) reservists who were ordered to active duty for thirty days or longer; (b) the unmarried spouses and children of deceased service members; and (c) retirees. Services at non-military facilities are sometimes provided for active duty members of the armed forces, as well. 10 U.S.C. §§1971-1104; 32 C.F.R. §199.4(a).

45. Humana Military Health Services (Humana) administers the Tricare/Champus program for the Tricare South Region, which includes the relevant states of Texas (excluding the El Paso area), Florida, Georgia, Louisiana, and Oklahoma. Humana requires providers to sign a Participation Agreement as a condition of participation in Tricare/Champus. Among other

things, the agreement mandates a provider "[t]o comply with applicable provisions of 32 C.F.R. 199 and related Tricare policy . . ." (TRICARE Policy Manual, Participation Agreement Requirements at p. 3, item 2.).

46. Defendants knew or recklessly disregarded the fact that their kickback scheme, the provision of unnecessary medical services, and the improper billing for the mixing of allergens and sublingual immunotherapy violate the FCA.

D. Other Government Healthcare Programs

47. The Federal Employees Health Benefits Program ("FEHBP") provides healthcare benefits for qualified federal employees and their dependents. It pays for various services, including those at issue here. Other Government Healthcare Programs include federal prison hospitals, Indian Health Services, Federal Employees' Compensation Act, Workers' Compensation Programs, Railroad Retirement Board, and Veterans Administration.

48. Reimbursement practices under all federally-funded government health care programs closely align with the rules and regulations governing Medicare reimbursement. Defendants knew or recklessly disregarded the fact that their kickback scheme, the provision of unnecessary medical services, and the improper billing for the mixing of allergens and sublingual immunotherapy violate the FCA.

E. The Anti-Kickback Statute

49. The Anti-Kickback Statute prohibits the knowing and willful offering, paying, solicitation, or receipt of remuneration in cash or in kind to induce or reward patient referrals or the generation of business involving any item or service payable by federal healthcare programs, including Medicaid, Medicare, Tricare/Champus, and other Government Healthcare Programs. 42 U.S.C. §1320a–7b. The AKS prohibits both the offer and the payment of kickbacks – by

those who offer or pay remuneration – and the solicitation or receipt of kickbacks – by those who solicit or receive remuneration. Compliance with the AKS is a condition of payment by Government Healthcare Programs.

50. In pertinent part, the AKS provides:

(b) Illegal remunerations

(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind –

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person –

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

* * * * *

> (g) Kickbacks. In addition to the penalties provided for in this section or section 1128A [42 USCS §1320a-7a], *a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of title 31, United States Code* [*the FCA*].

42 U.S.C. §1320a-7b, emphasis added. Violation of the AKS can also subject the perpetrator to exclusion from participation in Government Healthcare Programs and, effective August 6, 1997, civil monetary penalties of $50,000 per violation and three times the amount of remuneration paid. 42 U.S.C. §1320a-7(b)(7) and 42 U.S.C. §1320a-7a(a)(7).

51. The Anti-Kickback Act Statute is designed to, *inter alia* ensure that patient care will not be improperly influenced by inappropriate compensation from the healthcare industry. Each of the Government Healthcare Programs requires every provider who seeks payment from the program to promise and ensure compliance with the provisions of the Anti-Kickback Act and other federal laws governing the provision of healthcare services in the United States. Any claim that includes services resulting from a violation of the AKS, such as services by the physicians to whom the Defendants offered or paid kickbacks and the services provided by Defendants that resulted from kickbacks are false claims and other unlawful acts under the FCA and the State FCAs.

52. Payment of remuneration of any kind violates the AKS if one or any purpose for that remuneration was to induce referrals. Moreover, payments to physicians in return for the physicians' promises to send patients to a particular facility qualify as kickbacks, as do payments made to induce physicians to send patients to particular facilities. Giving a person the opportunity to earn money may also constitute an inducement under the Anti-Kickback Statute.

53. The Anti-Kickback Statute provides certain "safe harbors" to exclude specified conduct from its ambit, as long as the involved parties have strictly complied with all the conditions of the safe harbor. However, parties to an arrangement cannot obtain safe harbor

protection by entering into a sham contract that complies with the written agreement requirement of a safe harbor and appears, on paper, to meet all of the other safe harbor requirements, but does not reflect the actual arrangement between the parties.

54. There is a safe harbor for personal service arrangements which requires, among other things, that:

> The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs; and
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> * * * * *
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> The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

42 C.F.R. § 1001.952(d) (5), (7).

55. The financial agreements between the Defendants and the physicians whom Defendants paid remuneration are not protected by a safe harbor, where, as Relators learned - as further explained below - the physicians received a percentage of the gross collections generated by Defendants. This arrangement is impermissible because the compensation is based in part on the volume or value of services provided, and is not set in advance. Moreover, the Defendants' services are provided on an as-needed basis as opposed to being limited to a set schedule.

VI.
FACTUAL BACKGROUND

A. Appropriate Allergy Testing and Treatment Protocol

56. Each of the Relators is a board certified physician actively engaged in the practice of diagnosing, testing and treating individuals for allergies. They each provide care in

accordance with the practice parameters espoused by the Joint Task Force on Practice Parameters ("JTFPP") which represents the American Academy of Allergy, Asthma & Immunology ("AAAAI"), the American College of Allergy, Asthma & Immunology ("ACAAI"), and the Joint Council on Allergy, Asthma and Immunology ("JCAAI"). The practice parameters state that the objective of the parameters is to "optimize the practice of allergen immunotherapy for patients with allergic diseases . . . [and to] establish guidelines for the safe and effective use of allergen immunotherapy while reducing unnecessary variation in immunotherapy practice." Relators and other allergists consult these parameters when determining how best to diagnose, test and treat their allergy patients. These practice parameters have been recognized in the report "Allergen Immunotherapy for Medicare Beneficiaries" (OEI-09-00-00531), as establishing the standard of care for allergy treatment by the Office of Inspector General of the Department of Health and Human Services ("OIG"). Additionally, "CMS strongly encourages physicians who provide allergen immunotherapy to closely follow practice parameters agreed upon and endorsed by the professional societies that represent allergy, asthma and immunology (JCAAI) as long as those parameters fall within the coverage criteria of applicable LCDs." (MLN Matters #SE0812.)

57. Following these parameters, when a patient visits a physician office for diagnosis and treatment of potential allergies, the patient should first participate in an initial screening during which the physician or a member of the physician's staff interviews the patient about the patient's complaints. Then, if necessitated by the symptoms presented and the patient's exposure, the physician should order the appropriate allergy test, which is required to be conducted under the supervision of a physician.

58. One possible diagnostic test is a skin test. Generally, skin testing for allergy testing is covered by governmental healthcare programs. See e.g. Medicare Claims Processing Manual, Chapter 12 – Physicians/Nonphysician Practitioners, Section 200; Florida Medicaid Practitioner Services Coverage and Limitations Handbook, Chapter 2, Practitioner Services Covered Services, Limitations and Exclusions, Allergy Services, 2-9; Louisiana Professional Services Provider Manual, Chapter Five of the Medicaid Services Manual, Section 5.1, Covered Services, Allergy Testing; North Carolina Division of Medical Assistance, NCHC Policy No. NCHC2009.73, Allergy Immunotherapy; Texas Medicaid Provider Procedures Manual: Vol. 2, Medical and Nursing Specialists, Physicians, and Physician Assistants Handbook, Section 8.2.4.2.

59. A skin test is generally used to determine whether allergic antibodies are present within the patient. A skin test involves utilizing a skin testing device to insert certain allergens into the skin of the patient. Not all persons who have a justifiable need for allergy testing require expanded testing for all possible allergen sensitivities. The medically appropriate and cost effective selection of allergens for skin testing requires an option for skin testing individualization (i.e., allergy skin testing for sensitivity to trees, grasses, weeds, molds, and dust mites would be medically unnecessary for someone reporting allergic symptoms triggered only by cat and dog exposures.) For example, Dr. Vaughn has two types of non-food aeroallergen panel and two food panels, as well as individual allergens, which he uses on an as-needed basis, limiting his testing to individual allergen sensitivities if appropriate, based on the patient's clinical history. Dr. Stafford has three different aeroallergen panels and two food panels, as well as individual allergens, which he uses depending on each patient's age and clinical history. The

patient's clinical history should determine which panel and/or individual allergens the physician will utilize.

60. After the allergens are applied through the use of a skin testing device, the physician should then measure the patient's reaction to the allergens as compared to two control solutions – a saline solution (negative control) and a histamine solution (positive control) – to determine if the patient has experienced a reaction to each allergen. The patient's reaction must be examined within a specific period of time in order to be a reliable indicator of an allergic reaction. According to the JTF practice parameters for Allergy Diagnostic Testing (2008, p. S19), "a prick/ puncture test with a response of at least 3-mm diameter (with equivalent erythema) more than the diluent control done at the same time is required as proof of the presence of cutaneous allergen specific IgE." The physician should compare the results of the skin test to the patient's clinical history to determine whether the patient is allergic to particular allergen(s).

61. Another possible diagnostic test is a blood serum test, currently called "ImmunoCap", but also sometimes referred to as a "RAST" test (which is actually short for an older version of blood serum test). A RAST test is generally used when the patient history indicates a high possibility of anaphylactic reaction, when the patient's allergy history does not match the skin test results, and/or when the patient suffers from urticaria (hives) or other dermatologic processes. Some forms of hives may cause frequent false positives to a skin test. In cases of severe hives, the patient cannot be taken off antihistamines, making accurate skin tests impossible. Extensive skin testing is not warranted for chronic urticaria, but may be warranted in patients who might have allergic rhinitis and may also have chronic urticaria. For a RAST test, the patient's blood is typically drawn at an independent lab and then the results of the

test are shared with and analyzed by the physician. RAST or blood serum tests are not necessarily as accurate as skin tests.

62. Generally, RAST testing is covered by governmental health care programs when RAST testing is necessary. See e.g. Medicare Claims Processing Manual, Chapter 12 – Physicians/Nonphysician Practitioners, Section 200; Florida Medicaid Practitioner Services Coverage and Limitations Handbook, Chapter 2, Practitioner Services Covered Services, Limitations and Exclusions, Allergy Services, 2-9; Louisiana Professional Services Provider Manual, Chapter Five of the Medicaid Services Manual, Section 5.1, Covered Services, Allergy Testing; North Carolina Division of Medical Assistance, NCHC Policy No. NCHC2009.73, Allergy Immunotherapy; Texas Medicaid Provider Procedures Manual: Vol. 2, Medical and Nursing Specialists, Physicians, and Physician Assistants Handbook, Section 8.2.4.2.

63. If the results of either a skin test or a RAST test, coupled with the patient's clinical history, indicate that the patient is allergic to a specific allergen, the physician should then discuss the treatment options, which may include immunotherapy, with the patient. Prior to deciding whether the patient will receive immunotherapy, the physician should address the risks involved and whether the patient's symptoms justify those risks. Specifically, the physician should determine if the patient's allergies are well controlled by medication or whether certain life style changes could allow the patient to avoid the allergic trigger(s). Nationally, among the most severely allergic patients who are commonly referred to allergy specialists (or who self-refer), immunotherapy is used as a therapeutic option in only about 17% of these patients. (AAAAI Report on the Allergy and Immunology Physician Workforce, 1999-2009/10 (March 2012.))

64. If the patient and the physician agree that the patient will receive immunotherapy injections, or "allergy shots," the physician should determine which allergens will go into the immunotherapy mix. While some Relators personally mix the allergen combination used in the shots, others order the allergens premixed, according to the physician's prescription, which specifies the appropriate mix of allergens, from a third-party laboratory.

65. The physician's involvement in the choice of allergens and allergen concentrations to be included in an immunotherapy mix is critical to the likelihood for therapeutic success. Based on scientific studies, the optimal response to immunotherapy is dependent upon providing allergens to the patient within the "probable effective" dosage ranges (as published in the Immunotherapy Practice Parameters: Table IX., p.39). In the United States, the great majority of persons prescribed immunotherapy are "poly-sensitized' to multiple aeroallergens; thirty or more sensitivities are common. Frequently, due to volume constraints, not all skin test positive allergens can be added to an immunotherapy kit at "probable effective" doses. Consequently, the physician must rely upon the patient's clinical history to determine which allergen sensitivities are most clinically relevant to the individual's symptoms and thereby identify the allergens that must be represented in the mix at full strength and also identify minor allergens that can be provided either at sub-optimal doses or omitted completely without compromising the expected treatment efficacy. Allergy extract service providers often rely on the magnitude of either a skin test response to an allergen or the blood RAST testing level to select allergens or allergen doses for inclusion in immunotherapy. In addition, many allergy service providers often arbitrarily limit the number of included allergens to ten or fewer per treatment set (typically allowing for a maximum of twenty allergens). Since only the individual patient's clinical history is strongly indicative of the most important sensitivities, any mixing

protocols not based primarily on the patient's clinical history would result in sub-optimal therapeutic outcomes.

66. After developing the appropriate mix of allergens for the maintenance vial, each physician is responsible for diluting the mixture to an appropriate concentration for the beginning of the immunotherapy. Generally, physicians exercise this responsibility by training their staff to prepare a dilution set under physician supervision. Often, but with some variability, there is a maintenance vial produced and from this maintenance vial, additional diluted vials are made – a 10-fold dilution vial, a 100-fold dilution vial, and 1,000-fold dilution vial. For example, if a physician has a 5cc maintenance vial, the physician will extract 0.5 cc from the maintenance vial and then add that antigen mix to a vial containing 4.5 ccs of a dilution, creating the 10-fold dilution. From that 10-fold dilution, the physician will extract 0.5 cc and add that to another vial containing 4.5 ccs of the dilution. This process will continue until the desired concentration for the beginning of immunotherapy is reached.

67. The patient should first receive an injection from the most diluted vial and then should receive injections with a progressively increasing concentration of the immunotherapy mixture until the patient reaches what the physician considers to be the maintenance dose. This process provides a safe and effective treatment to the patients.

68. It is possible that during the course of immunotherapy the physician will determine that further dilution of the medication is necessary based upon the patient's reaction to an injection. Conversely, the physician may determine that a patient may be able to withstand a more concentrated dose depending on the patient's reaction to the immunotherapy.

69. According to the JTF practice parameters, maintenance immunotherapy is generally administered once or twice per month; this is a dosing regimen that has been proven to

be therapeutically effective in multiple clinical studies. The Medicare Benefits Policy Manual (Rev.140, 02-28-11) states "Medications administered for treatment of a disease and which exceed the frequency or duration of injections indicated by accepted standards of medical practice are not covered." (Chapter 15: 50.4.3(3)) UAL has chosen to administer maintenance immunotherapy at least twice per week, four times the rate necessary to achieve a good clinical outcome; this practice is designed to increase revenues for UAL by unnecessarily increasing costs to Government Healthcare Programs and other payors.

70. Except in extremely rare cases, the practice parameters require all such injections to be delivered in the physician's office by trained medical professionals, so that medical personnel will be available if a patient develops an adverse reaction, since these may be life threatening. After the injection is administered, the patient should remain in the physician's office for approximately thirty minutes, the time during which most adverse reactions develop, and be monitored for any adverse reaction. If none is detected, the patient leaves the office. If there is an adverse reaction, the physician will be present to administer the necessary treatment. Medicare specifically requires that treatment be provided under direct physician supervision, and the practice of routinely providing home immunotherapy is contrary to that requirement.

B. Sublingual Immunotherapy

71. SLIT therapy (administration of immunotherapy serums in the form of drops delivered under the tongue) has not been approved by the Food and Drug Administration. No CPT codes have been created which cover SLIT therapy. Therefore, if any medical professional elects to treat a patient through SLIT therapy, the patient must pay the full cost. SLIT therapy cannot be billed to a commercial insurance carrier or to any government healthcare program.

72. For example, as explained above, the Medicare National Coverage Determination Manual expressly states that "Medicare does not cover such antigens if they are to be administered sublingually, i.e., by placing drops under the patient's tongue. This kind of allergy therapy has not been proven to be safe and effective. *Antigens are covered only if they are administered by injection.*" (emphasis added). Medicare National Coverage Determination Manual, Ch. 1, Part 2, 110.9 – Antigens Prepared for Sublingual Administration.

73. Similar restrictions are imposed by the Texas Medicaid program. The Texas Medicaid Providers Procedures Manual, Vol. 2 – Medical and Nursing Specialists, Physicians, and Physician Assistants Handbook defines allergy immunotherapy as "the *parenteral* administration [i.e., subcutaneous or intramuscular injection] of allergenic extracts as antigens at periodic intervals, usually on an increasing dosage scale to a dosage which is maintained as maintenance therapy." (emphasis added). The manual goes on to specify that "allergen immunotherapy that is considered experimental, investigational, or unproven is not a benefit of Texas Medicaid."

74. Sublingual immunotherapy is also not covered by North Carolina's Medicaid program. NCHC Policy No. NCHC2009.73 specifically excludes sublingual immunotherapy, noting that it is considered investigational.

C. Appropriate Billing of Immunotherapy

75. As they do for all medical treatments, Government Healthcare Programs impose restrictions on the provision and billing of immunotherapy.

76. For example, the Medicare Benefit Policy Manual provides that "payment may be made for a reasonable supply of antigens that have been prepared for a particular patient if: (1) the antigens are prepared by a physician who is a doctor of medicine or osteopathy, and (2) the

physician who prepared the antigens has examined the patient and has determined a plan of treatment and a dosage regimen." A physician may also appropriately bill when he writes a prescription for the immunotherapy and has it prepared to his specifications.

77. Additionally, the Medicare Claims Processing Manual specifies that "if a patient's doses are adjusted, e.g., because of patient reaction, and the antigen provided is actually more or fewer doses than originally anticipated, the physician is to make no change in the number of doses for which he or she bills. The number of doses anticipated at the time of the antigen preparation is the number of doses to be billed . . . . This means that in cases where the patient actually gets more doses than originally anticipated (because dose amounts were decreased during treatment) and in cases where the patient gets fewer doses (because dose amounts were increased), no change is to be made in the billing." In other words, if a physician creates a 10 ccs maintenance vial, the most a physician can bill Medicare for is 10 ccs, regardless of how many doses the physician actually extracts from the vial. Likewise, if a physician creates a 5 ccs maintenance vial, the most a physician can bill Medicare for is 5 ccs, regardless of how many doses the physician extracts from the vial.

VII.
FACTUAL ALLEGATIONS

A. Defendants' AKS Violations

78. Defendants each individually have engaged in a scheme to pay kickbacks to primary care physicians in exchange for patient referrals for allergy testing and treatments.

79. Defendants market their scheme to PCPs to provide "in-office" allergy testing and treatment through the use of a Remote Allergy Center. The scheme requires the PCPs to provide a dedicated room and the Defendants to provide technicians and equipment. The PCPs then refer their patients to be tested for allergies by Defendants' technicians. For example, one of UAL's

Allergy Service Agreements states that UAL's responsibilities include "(1) the provision of [technicians] to perform allergy testing and mix antigens under the supervision of [the PCP] and (2) the provision of all supplies and equipment necessary to perform allergy testing, administer injections, and formulate, mix, store and label antigens." A true and correct copy At one time, UAL also provided billing services.

80. Most of the Defendants have their technicians perform a skin test to determine what allergens the patient reacts to; Allerta now utilizes a blood test but previously also used a skin test.

81. The Defendants' technicians interpret the test results, with no input from the PCPs. In some instances, Smart Allergy technicians photograph the skin test results and send them to an unknown location and to an unknown professional for interpretation and diagnosis. The PCPs bill for the testing and interpretation, as if the PCPs or their employees had performed the service, when in fact the services were performed by employees of Defendants without any supervision or involvement by the PCPs.

82. When patients are determined to have allergic sensitivities, immunotherapy serums are then provided by Defendants and Defendant's employees provide the PCPs specific instructions on how to bill for the service.

83. In most cases, the Defendants do not administer the majority of the injections. Instead, for example, according to UAL's protocols, the Defendants' technicians train patients to administer the injections themselves and send the patients home with the immunotherapy serum following their third injection. In at least one of UAL's contracts, UAL specifically states that UAL personnel only administer the patient's first immunotherapy injection and the patient's first immunotherapy injection of increased vial potency, leaving the patient to administer the rest.

Additionally, some Defendants provide sublingual immunotherapy instead of subcutaneous injections, but then bill or cause the PCPs to bill for immunotherapy injections.

84. Regardless of where the immunotherapy is provided, the PCPs assume responsibility for the delivery of medication of unknown type or quantity. And yet, when PCPs do attempt to exercise oversight and control over the Defendants' practices in the PCPs' offices, Defendants prevent the PCPs from doing so despite language in the services agreement which requires the PCPs to remain involved in the allergy testing and immunotherapy process. In fact, one dermatologist was so concerned about the lack of control he had over UAL's allergy activities, he terminated his contract with UAL, which then promptly sued the dermatologist for breach of contract.

85. In exchange for the services provided, the PCPs bill Government Healthcare Programs for these services as if they provided them, and then split the fee received from the government healthcare program with the Defendants. For example, in at least one of UAL's agreements with a PCP, the PCP agreed to pay UAL 60% of all collections received for services billed under CPT Billing Codes 95165 or 95004 or any successor codes thereto."

86. This scheme is heavily marketed to PCPs through materials such as a brochure entitled, "Does money really grow on trees?". The pamphlet plainly states that "UAL will place a highly trained medical assistant to perform all lab duties, assistance with paperwork, and handle patient scheduling at no cost to you."

87. This sample marketing material highlights the extensive financial benefits for physicians who partner with UAL, noting "By planting the UAL seed in your existing practice and working diligently together, we will both watch as the UAL money tree grows. This fruitful operation, engineered by UAL from the ground up, will be the profitable landscape for your

practices' future. **So in essence, money really does grow on trees.**" (Emphasis in original). According to UAL's marketing materials, "many doctors are collecting over $250,000 per year by implementing the program."

88. Even more troubling, the brochure boasts "no additional work necessary on behalf of the physician, staff, or billing dept. due to UAL handling each category with it's [sic] own personell [sic] at no additional cost." PCPs' lack of involvement and oversight with respect Defendants' activities in the Remote Allergy Centers makes it clear that the payments retained by the PCPs are kickbacks.

89. Smart Allergy's marketing materials make similar promises, touting the PCPs' ability to receive annual compensation that "easily exceed[s] $100,000." In addition to paying PCPs for the "services" they provide, Smart Allergy pays the PCPs rent for the space that Smart Allergy personnel use for the Remote Allergy Center, pays PCPs rent for the equipment and staff provided by Smart Allergy, and pays PCPs a portion of the immunotherapy income - which is by necessity based on the number of patients the PCPs refer for treatment.

90. By providing the medical services of skin testing and immunotherapy preparations without the required level of physician supervision to meet the applicable standards of care, and then splitting the fees with the PCPs, Defendants are engaged in a clear kickback scheme in violation of the AKS, FCA, and the State FCAs.

91. OIG Advisory Opinion No. 11-17 considered a hypothetical arrangement identical to the scheme put in place by Defendants and concluded "that the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute and that the Office of Inspector General could potentially impose administrative sanctions on [name redacted]."

92. In apparent recognition of the inherent problems with its contractual arrangement with PCPs, a more recent UAL Allergy Services Agreement states that "Practice Group shall pay to (UAL) a fixed fee for each allergy test administered and for the preparation of antigens for each year of allergen immunotherapy."

93. This revised scheme continues to violate the AKS, FCA, and state FCAs, as the services continue to be provided on an as-needed basis and the amount paid to UAL is directly dependent on the volume of patients referred by the PCPs to UAL.

94. According to UAL, under the terms of their 2012 contract, a PCP could make $262,384.00 in their first year, a significant sum given the fact that the average family practice physician makes approximately $200,000 per year. In essence, UAL is marketing a scheme that would enable family practice physicians to double their annual income, and over the life of the contract would enable them to earn more than $1 million.

B. Unnecessary Medical Services

95. Despite what the contracts purport to require, Relators have received information that Defendants recommend immunotherapy to more than 50% of patients who experience a skin reaction to the allergy testing. For UAL, between 60-70% of all patients tested are prescribed immunotherapy. When compared to the much lower national average of immunotherapy use by allergists, this extremely high percentage of patients who are prescribed immunotherapy at Defendants' Remote Allergy Centers suggests gross abuse of a potentially dangerous therapeutic option.

96. For example, Dr. Vaughn has provided second opinion consultations for sixteen patients who had been evaluated by UAL staff at UAL Remote Allergy Centers at the offices of five different PCPs. All of these patients had undergone medical screening and skin testing and

had been told that based on their results, they met the clinical criteria for the use of immunotherapy; all had been offered allergy treatment with immunotherapy. Dr. Vaughn's medical evaluations and allergy testing, he felt that only two of these sixteen patients (12.5%) met the clinical history and diagnostic criteria that would medically justify the use of immunotherapy (based on practice parameter recommendations).

97. In addition, among the sixteen UAL patients seen by Dr. Vaughn, eleven had been skin tested with biological extracts that were not at the time, and are not currently recommended by the practice parameters or standard of care for diagnostic testing or immunotherapy. These non-recommended biological extracts used by UAL are house fly, deer fly, moth, mosquito, tobacco, mouse epithelium, and fire ant venom. Under the current recommended standards of care, testing for fire ant allergy is recommended only for those patients who report severe allergic reactions to fire ant stings; none of the eleven patients seen by Dr. Vaughn who had been tested with these biological extracts had reported a history that would support the use of this testing (or immunotherapy). UAL later modified its testing panel by dropping all of the identified inappropriate allergens, but UAL then selected several replacement tree allergens that are not geographically present and are not tested by the regional allergists, including Shagbark Hickory, Beech, Sweet Gum and Black Walnut. Testing for non-indigenous allergens and then providing immunotherapy treatment for a detected but clinically irrelevant sensitivity does not meet the standard of care and would not be expected to provide therapeutic benefit to the patient. In fact, injecting inappropriate allergens into patients or using clinically irrelevant allergens in immunotherapy places the patient at risk for developing new sensitivities and also needlessly increases the risk for a serious allergic reaction to the injection.

98. Dr. Vaughn first became aware of the potential dangers of UAL skin testing for atypical (non-traditional) allergens in 2009 when patient K.L. sought his expert opinion after she had been skin tested at a UAL Remote Allergy Center for multiple atypical allergens and had experienced an adverse reaction that necessitated a transfer to an emergency room by EMS. It was Dr. Vaughn's opinion that K.L had suffered an anaphylactic reaction during testing and he then performed a RAST test for approximately 24 or 25 common aeroallergens present in San Antonio, where the patient lived. The RAST test revealed that the patient reacted only to cat dander; however, the patient had cats in her home and did not experience any allergic symptoms. Dr. Vaughn hypothesized that the patient must have reacted to one of the "non-traditional" allergens tested by UAL technicians – housefly, deer fly, moth, tobacco or mosquito, none of which would be tested under the appropriate standard of care. In addition, Dr. Vaughn saw a patient (C.H.) who had received UAL immunotherapy that contained atypical allergens house fly, mosquito, mouse epithelium, and fire ant, as well as several other traditional aeroallergens. Closely following an immunotherapy injection, C.H. experienced an allergic reaction that necessitated an EMS transport to an emergency room. Since the RAST allergy testing subsequently performed by Dr. Vaughn failed to identify sensitivity to any traditional allergens, his hypothesis was that this patient had suffered an adverse reaction to one of the atypical allergens included in his immunotherapy by UAL and had unjustifiably been placed on UAL immunotherapy.

99. All told, Dr. Vaughn has seen sixteen different patients who had been "tested" for allergies by UAL at Remote Allergy Centers at their PCPs' offices using skin testing panels that contained several regionally irrelevant airborne allergens. In addition, all skin tests had been graded using criteria for positive interpretation that failed to meet the standard of care.

Consequently, many of these patients were prescribed immunotherapy that contained clinically irrelevant allergens that needlessly exposed them to a risk for anaphylaxis.

100. Each of these patients had been tested with virtually the same panel of allergens, without regard to any allergic symptoms with which they presented. In contrast, the Relators order (and the appropriate standard of care requires) a test panel for each patient based on their history, symptoms, geographic location, and exposure.

101. Dr. Freeman learned of UAL's questionable allergy test panels when he was contacted by a dermatologist who had been utilizing UAL's services. The dermatologist contacted Dr. Freeman seeking his professional medical opinion about a law suit impacting the dermatologist. Based on his review of the records provided by the dermatologist, Dr. Freeman learned that UAL tested the dermatologist's patients with a standard panel of 50 antigens either on the patient's back or arm. The results were then reviewed by the non-physician UAL employee and "reactions" documented without regard to whether the reaction is more than 3 mm larger than the negative control as recommended by the JTF practice parameter and the standard of care. The UAL employee sent out the test results for the formulation of the immunotherapy. Once the immunotherapy was prepared, the UAL employee administered the immunotherapy in the office as injections or sublingually.

102. Dr. Stafford learned of Smart Allergy Labs' improper testing procedures when he treated a patient who was suffering from chronic urticaria or hives. Despite the fact that hives do not respond to immunotherapy, the patient had been tested by SAL in a Remote Allergy Center at a PCP's office and prescribed a course of immunotherapy. In this patient's case, neither the testing nor the treatment with immunotherapy was warranted. Testing in Dr. Stafford's office confirmed that the allergy tests done in the primary physician's office were inaccurate. Yet the

patient was billed for allergy testing and received a bill for $18,000 for four immunotherapy vials.

103. Dr. Stafford has seen records of patients who were allergy tested by SAL and UAL with inappropriate antigens such as housefly, deerfly, moth and tobacco. These patients were also prescribed immunotherapy even though their skin test results were often invalid or failed to demonstrate allergy based on internal controls.

104. Dr. McKenna has seen numerous patients who had been "treated" in Defendant Allerta's Remote Allergy Centers. For example, one patient presented with a history of hives and swelling but denied any respiratory symptoms, one of the hallmarks of an allergy which could respond to immunotherapy. More importantly, both Medicare and Medicaid have approved immunotherapy only in certain situations – and not when the patient is presenting with hives.

105. Despite this, Dr. McKenna's patient was subjected to a test with a broad spectrum of allergens, including numerous aeroallergens. In addition, the patient was placed on allergen immunotherapy inappropriately for hives. Upon further examination by Dr. McKenna, he determined that the patient's hives and swelling would be not helped by immunotherapy. Nonetheless, Allerta placed her on immunotherapy. Allerta's allergy testing of and providing immunotherapy to this patient, and others like her, subjected her to needless risks, including anaphylaxis.

106. Dr. McKenna also reviewed records for numerous patients who were tested in Allerta's Remote Allergy Centers for a broad spectrum of "allergens", including substances that were either not indicated as reasonably necessary from a medical perspective based on symptoms presented or were not allergens at all.

107. In addition to ignoring the recommended 3-mm cut-off value for a positive skin test interpretation as advocated by the JTF practice parameter "Allergy Diagnostic Testing," UAL also ignores the recommended 3-mm cut-off value clearly printed on the skin test grading ruler provided by the manufacturer (Hollister-Steir) for the "ComforTen" skin test device they have used. UAL's profit motivated decision to use diagnostic skin test grading criteria below the standards of care (by designating reactivities as small as 1-mm larger than the negative control as positive reactions) has falsely identified some patients as allergic and has also led to the inclusion of potentially dangerous false positive allergens in immunotherapy. In addition, UAL's choice to lower the threshold for the diagnosis of a positive skin test reaction has an additional financial benefit; since mold allergens are typically isolated from other allergens in a separate immunotherapy treatment kit, each time a false positive mold sensitivity is identified, a second treatment set becomes necessary and resultantly, the billing for the number of required immunotherapy doses doubles. A similar situation arose with a UAL patient Dr. Vaughn saw. In that case, the patient was tested with horse allergen even though the patient was not exposed to horse, and when a sensitivity was recorded, UAL used it to justify the upcharge for a second immunotherapy treatment kit.

108. By indiscriminately testing for and prescribing immunotherapy for patients who do not need it, and violating the standards of care in the testing and prescribing of immunotherapy, Defendants are providing unnecessary and improper medical services. These services place patients at risk of harm, improperly cost Government Healthcare Programs vast sums of money, and in some cases of immunotherapy shortages, affect the availability of sufficient allergens for other people who actually need them.

C. Improper Billings for the Mixing and Dilutions of Allergens

109. As discussed above, Medicare and Medicaid imposes strict restriction on the billing of allergen immunotherapy.

110. Once a patient is determined to be an appropriate candidate for immunotherapy, the physician should prescribe the appropriate serum for the injections, determining the appropriate mix of antigens. Once the serum is received by the physician, the physician should dilute the serum to appropriate level to begin the immunotherapy. Generally, the standard of care requires several different levels of dilutions, with the concentration of the allergens increasing, until the maintenance dose level is reached.

111. According to Medicare guidelines, a physician can bill only once for the creation and dilution of the serum. Should it become apparent during the course of the immunotherapy that additional dilutions are necessary to achieve the best medical results, such dilutions should be made. However, Medicare prohibits a physician from billing for any subsequent dilutions.

112. Certain states also impose specific restrictions on the billing of mixing allergens. For example, Florida Medicaid states that "preparation of a multiple allergen vial may be reimbursed only once per treatment cycle." Illinois Medicaid provides that "allergenic extract should only be billed when each new vial of antigen is prepared."

113. In blatant disregard for these requirements, UAL bills, and/or causes the PCPs to bill, Government Healthcare Programs multiple times for the same treatment set. UAL, and upon information and belief the other Defendants as well, mix treatment sets, bill, and/or cause PCPs to bill, for them, and then on multiple subsequent days bill for the creation of the same treatment sets. This wrongful practice greatly increases the Defendants' revenue and the revenue of the PCPs with whom they contract and violates the billing requirements of the Government Healthcare Programs.